

Exhibit B

1 James R. Condo (#005867)
Amanda C. Sheridan (#027360)
2 SNELL & WILMER L.L.P.
One Arizona Center
3 400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
4 Telephone: (602) 382-6000
jcondo@swlaw.com
5 asheridan@swlaw.com

6 Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
7 Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
8 NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
9 201 17th Street, NW, Suite 1700
Atlanta, GA 30363
10 Telephone: (404) 322-6000
richard.north@nelsonmullins.com
11 matthew.lerner@nelsonmullins.com

12 *Attorneys for Defendants*
C. R. Bard, Inc. and
13 *Bard Peripheral Vascular, Inc.*

14 **IN THE UNITED STATES DISTRICT COURT**
15 **FOR THE DISTRICT OF ARIZONA**

16 IN RE: Bard IVC Filters Products Liability
17 Litigation

No. 2:15-MD-02641-DGC

18 **DECLARATION OF ROBERT**
CARR IN SUPPORT OF
DEFENDANTS' MOTION TO SEAL
DOCUMENTS FILED BY
PLAINTIFFS IN OPPOSITION TO
DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT
REGARDING PREEMPTION

(Assigned to the Honorable David G.
Campbell)

25 I, Robert Carr, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that
26 the following is true and correct to the best of my knowledge and belief:

27 1. I am over 18 years of age and am competent to testify about the matters
28

1 contained herein. The statements contained herein are based on my personal knowledge and
2 upon the basis of the documents maintained by Defendants C. R. Bard, Inc. and Bard
3 Peripheral Vascular, Inc. (collectively, "Bard") in the regular course of business.

4 2. I am presently employed as the Vice President of International at Bard
5 Peripheral Vascular, Inc. ("BPV") a subsidiary of C. R. Bard, Inc. ("C. R. Bard"). Until
6 October 2015, I was Senior Director of Research and Development at BPV. Bard
7 manufactures and distributes inferior vena cava ("IVC") filters and has manufactured and
8 distributed the Recovery® Filter, G2® Filter, G2® Express Filter, G2®X Filter, Eclipse®
9 Filter, Meridian® Filter, and Denali® Filter (collectively, "Bard IVC Filters"), each of
10 which is a medical device cleared by the Food and Drug Administration ("FDA")
11 indicated for treatment of blood flow problems posing the risk of pulmonary embolism.
12 Before joining BPV in 2002, I was employed by Nitinol Medical Technologies ("NMT"),
13 where I was also responsible for that company's research and development of IVC filters.

14 3. This declaration is based upon my personal knowledge and review of certain
15 business records prepared and maintained in the ordinary course of business of Bard
16 regarding the design, testing, marketing, and product assessment of its IVC filters and of
17 certain public records that set out FDA's regulatory activities concerning Bard's IVC
18 Filters. I could and would competently testify to the matters set forth herein if called as a
19 witness in this matter. As part of and during the course of my work with Bard and NMT,
20 I have become familiar with documentation and records associated with the design,
21 development, manufacture, regulatory compliance, testing (including clinical testing),
22 marketing and product assessment of the Bard IVC Filters.

23 a. The documentation and records include, for example, 510(k) submissions, IDE
24 submissions, and other materials sent to FDA, as well as contact reports and email
25 communications with the FDA, which detail Bard's product development and
26 regulatory compliance activities of Bard's IVC Filters.

27 b. The documentation and records also include internal documents prepared by the
28 FDA, a public federal agency. These records or statements of a public office detail

1 the agency's investigation and regulatory review activities of Bard's regulatory
2 compliance and product development activities concerning Bard's IVC Filters.

3 c. The documents created during the design and development of Bard's IVC Filters,
4 including testing and product assessment.

5 d. Bard's internal marketing and regulatory compliance procedures.

6 e. Bard' product analysis and evaluation processes and review of product
7 performance.

8 f. Confidential deposition testimony regarding the documents or Bard's internal
9 business practices.

10 4. As part of and during the course of my work with Bard, I have become
11 familiar with Bard's record-keeping procedures. I have personal knowledge of the roles
12 and responsibilities of Bard's employees responsible for this record-keeping process. The
13 business documents referenced herein were prepared and maintained in the ordinary
14 course of Bard's business, and it was the regular practice of Bard to make such records.
15 These documents were prepared at or near the time of the events they record by persons
16 with knowledge of the recorded events or from information transmitted by persons with
17 knowledge of the recorded events.

18 5. Bard or its affiliates are engaged in the development, design, manufacturing,
19 and distribution of medical devices, including the Bard Filters. Many documents
20 involving the Bard IVC Filters are confidential and are maintained as such by Bard for the
21 reasons listed below.

22 6. The medical device business for IVC filters is a highly technical and
23 sophisticated industry. It is also a highly competitive industry in which each company
24 carefully guards its company documents, data, systems, processes, research and
25 development, analysis, marketing strategies and trade secrets from competitors.

26 7. As part of and during the course of my work with Bard, I have become
27 familiar with Bard's efforts to protect its trade secret and confidential proprietary
28 information and documents. This information is maintained internally at Bard and

distributed to employees who need to know the information to perform their duties. It is not available outside the company. Outside physician consultants working with the company who have access to this information sign confidentiality agreements. Additionally, Bard has always sought a Protective Order or Confidentiality Agreement during the course of civil lawsuits in order to protect their confidential, proprietary and trade secret information

8. As part of and during the course of my work with Bard and NMT (before Bard acquired the NMT filter product line), I have become familiar with documentation and records associated with the design, development, manufacture, regulatory compliance, testing (including clinical testing), product analysis and adverse event reports of the Bard IVC Filters.

9. I am familiar with the exceptions to the Freedom of Information Act ("FOIA"). Specifically FOIA recognizes an exception for trade secrets, and confidential commercial and financial information. When FDA makes a production, it redacts confidential and trade secret information provided by medical device companies such as Bard including: drafts of documents; testing protocols; test methods, results and analysis; design protocols; DFMEA (Design Failure Modes and Effects Analysis); engineering drawings; and other documents created during the design of a medical device.

10. Attached as Exhibit "A" is a list of the confidential documents lodged under seal by Plaintiffs on September 1, 2017. The documents are redacted to protect Bard's trade secrets and confidential information including:

- a. Documents created during the design of Bard's IVC Filters (including DFMEA);
- b. Test procedures and results regarding Bard's IVC Filters;
- c. Internal marketing and regulatory analysis;
- d. Internal product analysis both through studies and based on adverse event reporting;
- e. Internal communications to employees regarding analysis of Bard's IVC filters.

Nelson Mullins Riley & Scarborough

LLP
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

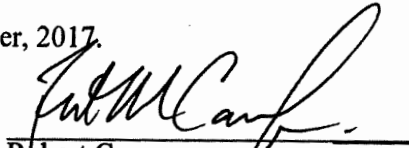
1 11. The redacted information contained in the documents referenced in Exhibit
2 "A" required years for Bard to develop and is Bard's critical business information which
3 is not made public by Bard.

4 12. The redacted information contained in the documents referenced in Exhibit
5 "A" would be of economic value to Bard's competitors. Moreover, such value would
6 extend not only to manufacturers of other IVC filters, but also to manufacturers of other
7 medical devices, as the value and utility of this information is not limited to IVC filters.

8 13. Bard invests very substantial sums of money in medical device research,
9 testing (including clinical testing), development, design, analysis, regulatory compliance,
10 product evaluation, and marketing. If the information Bard has developed over the years
11 pertaining to the Bard IVC Filters was obtained by its competitors, it would give an unfair
12 economic advantage to those competitors.

13 I declare under penalty of perjury, under the laws of the United States, that the
14 foregoing is true and correct.

15 Executed on this 11th day of September, 2017.

16
17 
18 Robert Carr
19
20
21
22
23
24
25
26
27
28